UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GREGG MATTERN and RAQUEL MATTERN, **Plaintiffs,** **v.** **BIOMET, INC.; BIOMET ORTHOPEDICS, LLC; BIOMET FAIR LAWN, LLC; BIOMET FAIR LAWN, LP; and DOES 1-10 inclusive,** **Defendants.**	**Civil Action No.: 12-4931 (ES)** **OPINION**

SALAS, DISTRICT JUDGE

I. INTRODUCTION

Pending before this Court is Defendants, Biomet Fair Lawn, LLC and Biomet Fair Lawn, L.P.'s (collectively "Biomet Fair Lawn" [1] or "Defendants") unopposed motion to dismiss Plaintiffs Gregg and Raquel Mattern's (collectively "Plaintiffs") Complaint pursuant to 21 U.S.C. § 1605(a). (D.E. No. 7-1, Defs.' Biomet Fair Lawn LLC & Biomet Fair Lawn L.P.'s Mem. of Law in Supp. of Mot. to Dismiss (the "Motion")).[2] The Court has jurisdiction pursuant to 28 U.S.C. § 1332(a)(1). The Court has reviewed the Defendants' submission and decides the Motion without oral argument pursuant to Fed. R. Civ. P. 78(b). For the reasons set forth below, Defendants' motion to dismiss is GRANTED.

[1] Effective February 29, 2008, Biomet Fair Lawn was converted from a limited partnership into a limited liability corporation. (D.E. No. 7-5, Articles of Entity Conversion of Biomet Fair Lawn, LLC at 5).

[2] This Opinion only addresses Defendants Biomet Fair Lawn, LLC and Biomet Fair Lawn, L.P. Defendants. Biomet, Inc. and Biomet Orthopedics, LLC answered the Complaint on August 13, 2012. (D.E. No. 6, Defs. Biomet, Inc. and Biomet Orthopedics, LLC's Answer and Separate Defenses to Pls.' Compl. ("Answer")).

II. BACKGROUND

Plaintiff Gregg Mattern seeks damages for injuries he sustained following a right hip replacement involving the M^2a-Taper™ Hip Replacement System (the "Device") metal-on-metal hip implant. (D.E. No. 1-1, Complaint ("Compl.") ¶¶ 36, 46-71). Defendants performed casting operations in the manufacture of the Device. (*Id.* ¶ 11). Plaintiffs assert a product liability claim under New Jersey law and a claim for punitive damages. (*Id.* ¶¶ 46-74). Plaintiff Raquel Mattern also alleges loss of consortium. (*Id.* ¶¶ 72-74). Biomet Fair Lawn seeks to dismiss the Complaint pursuant to the Biomaterials Access Assurance Act ("BAAA" or the "Act").

III. LEGAL STANDARD

For a complaint to survive dismissal, it "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). In determining the sufficiency of a complaint, the Court must accept all well-pleaded factual allegations in the complaint as true and draw all inferences in favor of the non-moving party. *See Phillips v. Cnty. of Allegheny*, 515 F.3dd 224, 231 (3d Cir. 2008). But, "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions[;] [t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 687.

Under the BAAA, however, Congress has provided its own standard to dismiss a complaint. *See* 21 U.S.C. §§ 1601-1606. The Act applies to "any civil action brought by a claimant, whether in a Federal or State court, on the basis of any legal theory, for harm allegedly caused, directly or indirectly, by an implant." *Id.* § 1603(b)(1). It provides that "[a] defendant

may, at any time during which a motion to dismiss may be filed under applicable law,[3] move to dismiss an action against it on the grounds that the defendant is a biomaterials supplier," and if the defendant: (1) is not "liable as a manufacturer"; (2) is not "liable as a seller"; and/or (3) is not "liable for furnishing raw materials or component parts for the implant that failed to meet applicable contractual requirements or specifications." *Id.* § 1605(a)(1)-(3); *see also Whaley v. Morgan Advanced Ceramics, Ltd.*, No. 07-cv-00912, 2008 WL 901523, at *2-3 (D. Colo. Mar. 31, 2008) (dismissing biomaterials supplier because it was not the implant's manufacturer or seller, and it did not furnish raw materials or components that failed to meet contractual requirements or specifications).

Under the BAAA motion to dismiss, the Court must rule solely on the basis of the pleadings and any affidavits submitted under §§ 1605(c)(2)(A) and (B). 21 U.S.C. § 1605(c)(3); *see also Marshall v. Zimmer*, No. 99-093-E, 1999 WL 34996711, at *3 (S.D. Cal. Nov. 4, 1999) (The Act "is quite clear that the suppliers can provide affidavits to demonstrate that they are not subject to litigation for their minimal contribution to a medical device ultimately designed, made, and sold by the manufacturer."). Thus, the Act allows trial courts to dismiss biomaterials suppliers from lawsuits prior to discovery.[4] 21 U.S.C. § 1605(c)(2)(A)-(B). Further, under §1605(e), dismissal must be made with prejudice.

IV. DISCUSSION

The BAAA protects parties who supply either raw materials or component parts for medical implants ("biomaterials suppliers") from the expenses of implant failure litigation by providing "expeditious procedures to dispose of unwarranted suits against the suppliers." 21 U.S.C. § 1601(15)(B). One such procedure is a motion to dismiss, which a biomaterials supplier

[3] The applicable law permitting the instant motion is Fed. R. Civ. P. 12(b)(6).
[4] Neither party has requested discovery under 21 U.S.C. § 1605(c)(1)(B)(i) or (ii).

may file under 21 U.S.C. § 1605(a). To prevail under a BAAA motion to dismiss, Biomet Fair Lawn must demonstrate that it: (1) is a "biomaterials supplier"; (2) is not a manufacturer of the failed implant; (3) is not a seller of the failed implant; and (4) did not provide raw materials or component parts that failed to meet applicable contractual requirements or specifications. *Id.* § 1605(a)(1)-(3); *see also Whaley*, 2008 WL 901523, at *1. Biomet Fair Lawn is a biomaterials supplier under the BAAA. Biomet Fair Lawn was not the manufacturer or seller of the Device, nor did it furnish raw materials or component parts that failed to meet contractual requirements or specifications. Thus, as a biomaterials supplier, Biomet Fair Lawn is not liable for Plaintiffs' harm.

A. Biomaterials Supplier

Under the BAAA, a "biomaterials supplier" is "an entity that directly or indirectly supplies a component part or raw material for use in the manufacture of an implant." 21 U.S.C. § 1602(1)(A). A "component part" is "a manufactured piece of an implant," including a piece that: "(i) has significant non-implant applications; and (ii) alone, has no implant value or purpose, but when combined with other component parts and materials, constitutes an implant." *Id.* § 1602(3). A "raw material" is "a substance or product that[:] (A) has a generic use; and (B) may be used in an application other than an implant." *Id.* § 1602(8).

Biomet Fair Lawn is a casting manufacturer whose sole role in the manufacturing process is to shape a raw piece of metal that will eventually become an implant.[5] (D.E. No. 7-4, Decl. of

[5] Mark Moudy, Biomet Fair Lawn, LLC's Director of Operations, provides a description of Defendants' role in the manufacturing process:

> Biomet Fair Lawn, LLC uses a casting method called investment casting. Investment casting starts with a wax pattern of the part to be made. Multiple wax patterns are then created from the model wax pattern. These wax patterns are then attached to a wax sprue, resulting in a pattern cluster, or tree, with the sprue as the trunk and the branches as the parts. The tree is then coated with ceramic material. Once the ceramic material is hardened and heated, it takes the shape of the wax pattern. The wax is then melted out of the shell, leaving

Mark Moudy ("Moudy Decl.") ¶¶ 3-4). It uses raw chromium and cobalt metals (which have many uses other than medical device manufacturing) to create the metal castings that later become parts of the Device. (*Id.* ¶ 6). The castings created by Biomet Fair Lawn are not completed medical devices and could not be implanted into a human being without additional manufacturing steps and quality checks. (*Id.* ¶ 7). Biomet Fair Lawn does not conduct or control these manufacturing steps—of which there are over twenty. (*Id.* ¶ 4). Accordingly, Biomet Fair Lawn is a biomaterials supplier under the BAAA.

B. Liability as a Manufacturer

Biomet Fair Lawn is not liable as a manufacturer under the BAAA. A biomaterials supplier may be liable as a manufacturer "of the implant that allegedly caused harm to a claimant only if" it: (1) "registered or was required to register with the Secretary [of Health and Human Services] pursuant to [the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 360)] and the regulations issued under such section;" and (2) "included or was required to include the implant on a list of devices filed with the Secretary pursuant to section 360(j) of this title and the regulations issued under such section." 21 U.S.C. § 1604(b)(2)(A). A biomaterials supplier may also be liable as a manufacturer if it was required, but failed, to complete either of the above factors and "is the subject of a declaration issued by the Secretary." *Id.* § 1604(b)(2)(B). Biomet Fair Lawn is not registered with the Secretary of the Department of Health and Human Services,

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> a cavity. Next, a raw material ingot (a chunk of metal) is melted in a furnace and, upon reaching a certain temperature, is poured into the cavity. The metal solidifies within the ceramic mold, and the ceramic shell is removed. The resulting metal castings are then removed from the tree and subjected to extensive testing including x-ray, dye penetrant, and visual inspection. Upon completion, the castings are sent on to other manufacturing facilities owned and operated by other companies affiliated with Biomet, Inc. for next steps in the manufacturing process.

(D.E. No. 7-4, Moudy Decl. ¶ 4).

as it is not required to do so.[6] (D.E. No. 7-4, Moudy Decl. ¶ 8). Further, it is not required to list and has never listed a Biomet hip implant (or any other Biomet device) on a 21 U.S.C. § 360(j) device list. (*Id.*). Biomet Fair Lawn, therefore, is not liable as a manufacturer.

C. Liability as a Seller

Biomet Fair Lawn is not liable as a seller under the BAAA. A "seller" is defined as "a person who, in the course of a business conducted for that purpose, sells, distributes, leases, packages, labels, or otherwise places an implant in the stream of commerce." 21 U.S.C. § 1602(10). A biomaterials supplier may be liable as a seller only if it "held title to the implant and then acted as the seller of the implant after its initial sale by the manufacturer" or "acted under contract as a seller to arrange for the transfer of the implant directly to the claimant after the initial sale by the manufacturer of the implant." *Id.* § 1604(c)(1). Biomet Fair Lawn did not market, sell, distribute, lease, or package the metal-on-metal hip implants. (D.E. No. 7-4, Moudy Decl. ¶ 9). Further, Biomet Fair Lawn did not develop or publish the package inserts, labels, or marketing materials; nor did it have any involvement with the warnings or instructions relating to them. (*Id.* ¶ 10). As such, Biomet Fair Lawn is not liable as a seller under the BAAA.

A biomaterials supplier may also be liable as a manufacturer or seller if it is "related by common ownership or control to a person meeting" these requirements, and if the court finds that the related manufacturer or seller "lacks sufficient financial resources to satisfy any judgment that the court feels it is likely to enter should the claimant prevail." 21 U.S.C. §§ 1604(b)(2)(C), (c)(2). Although Biomet Fair Lawn is related to the other defendants by common ownership, there is no basis for this Court to find that the other defendants lack sufficient financial resources to satisfy a judgment. In fact, the other Defendants, Biomet, Inc. and Biomet Orthopedics, LLC

[6] *See* 21 U.S.C. § 360. Biomet, Inc. registered the Device on December 6, 2000. (*See* D.E. No. 7-3, Dec. 6, 2000, Food and Drug Admin., Dept. of Health & Human Servs. Letter ("FDA Clearance")).

answered the Complaint, indicating they have, at the very last, sufficient financial resources to litigate the instant matter. (*See* D.E. No. 6, Answer).

D. Contractual Requirements or Specifications

Under the BAAA, a biomaterials supplier may "be liable for harm to a claimant caused by an implant if the claimant in an action shows, by a preponderance of the evidence," that the biomaterials supplier "fail[ed] to meet applicable contractual requirements or specifications." *Id.* § 1604(d). Additionally, the failure to meet the contractual specifications must be "an actual and proximate cause of the harm to the claimant." *Id.* § 1604(d)(2). Biomet Fair Lawn's castings for metal-on-metal implants are manufactured in accordance with specifications provided by Biomet, Inc. and/or Biomet Orthopedics, LLC.[7] (D.E. No. 7-4, Moudy Decl. ¶ 5). Furthermore, Plaintiffs' complaint makes no allegations against Biomet Fair Lawn of any issues, failures, or defects in castings. (*See* D.E. No. 1-1, Compl.). Therefore, there is no reason to believe that the parts purchased by or for Plaintiff Gregg Mattern failed to meet contractual requirements or specifications. (D.E. No. 7-4, Moudy Decl. ¶ 5).

V. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is GRANTED.

s/ Esther Salas
Esther Salas, U.S.D.J.

[7] Biomet Fair Lawn manufactures the castings in response to orders issued by Biomet, Inc.'s Material Resource Planning (MRP) system, a production planning and inventory control system used by Biomet, Inc. to manage manufacturing processes. (D.E. No. 7-4, Moudy Decl. ¶ 5). The MRP System automatically notifies manufacturing units, like Biomet Fair Lawn, when parts inventory is low. (*Id.*).